

CHAPTER 7. REGULATIONS AND GUIDELINES

Pertinent international and national regulations, advisories, and guidelines regarding *N*-nitrosodiphenylamine in air, water, and other media are summarized in Table 7-1. This table is not an exhaustive list, and current regulations should be verified by the appropriate regulatory agency.

ATSDR develops MRLs, which are substance-specific guidelines intended to serve as screening levels by ATSDR health assessors and other responders to identify contaminants and potential health effects that may be of concern at hazardous waste sites. See Section 1.3 and Appendix A for detailed information on the MRLs for *N*-nitrosodiphenylamine.

Table 7-1. Regulations and Guidelines Applicable to *N*-Nitrosodiphenylamine

Agency	Description	Information	Reference
Air			
EPA	RfC	No data	IRIS 2002
WHO	Air quality guidelines	No data	WHO 2010
Water & Food			
EPA	Drinking water standards and health advisories	No data	EPA 2012
	National primary drinking water regulations	No data	EPA 2009
	RfD	No data	IRIS 2002
WHO	Drinking water quality guidelines		WHO 2017
	Guideline value	0.0001 mg/L (0.1 µg/L) ^a	
FDA	EAFUS	No data ^b	FDA 2013
Cancer			
ACGIH	Carcinogenicity classification	No data	ACGIH 2016
HHS	Carcinogenicity classification	No data	NTP 2016
EPA	Carcinogenicity classification	B2 ^{c,d}	IRIS 2002
	Oral slope factor	4.9x10 ⁻³ (mg/kg/day) ⁻¹	
IARC	Carcinogenicity classification	Group 3 ^e	IARC 2017
Occupational			
ACGIH	TLV	No data	ACGIH 2016
OSHA	PEL (8-hour TWA) for general industry, shipyards and construction	No data	OSHA 2016a , 2016b , 2016c
NIOSH	REL (up to 10-hour TWA)	No data	NIOSH 2016

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Table 7-1. Regulations and Guidelines Applicable to N-Nitrosodiphenylamine

Agency	Description	Information	Reference
Emergency Criteria			
EPA	AEGLs-air	No data	EPA 2016
AIHA	ERPGs	No data	AIHA 2015
DOE	PACs-air		DOE 2016a
	PAC-1 ^f	5.5 mg/m ³	
	PAC-2 ^f	60 mg/m ³	
	PAC-3 ^f	360 mg/m ³	

^aBased on hepatic biliary cystadenomas in female rats, the most sensitive carcinogenic end-point, observed in a drinking-water study, using a multistage model.

^bThe EAFUS list of substances contains ingredients added directly to food that FDA has either approved as food additives or listed or affirmed as GRAS.

^cGroup B2: probable human carcinogen.

^dBased on increased incidence of bladder tumors in male and female rats and reticulum cell sarcomas in mice, and structural relationship to carcinogenic nitrosamines.

^eGroup 3: not classifiable as to its carcinogenicity to humans.

^fDefinitions of PAC terminology are available from U.S. DOE (2016b).

ACGIH = American Conference of Governmental Industrial Hygienists; AEGL = acute exposure guideline levels; AIHA = American Industrial Hygiene Association; DOE = Department of Energy; EAFUS = Everything Added to Food in the United States; EPA = Environmental Protection Agency; ERPG = emergency response planning guidelines; FDA = Food and Drug Administration; GRAS = generally recognized as safe; HHS = Department of Health and Human Services; IARC = International Agency for Research on Cancer; IRIS = Integrated Risk Information System; NIOSH = National Institute for Occupational Safety and Health; NTP = National Toxicology Program; OSHA = Occupational Safety and Health Administration; PAC = Protective Action Criteria; PEL = permissible exposure limit; REL = recommended exposure limit; RfC = inhalation reference concentration; RfD = oral reference dose; TLV = threshold limit value; TWA = time-weighted average; WHO = World Health Organization